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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,084	04/15/2004	Jeffery R. Raymond	480117.412	7178

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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12/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,084	Applicant(s) RAYMOND ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
 4a) Of the above claim(s) 5,6,9-21 and 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,22 and 23 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/5/07, 3/31/05, 8/27/04</u> . | 6) <input type="checkbox"/> Other: ____ |

First Office Action on the Merits

Election/Restrictions

1. Applicant's election without traverse of Group I and the compound #78 found in the present specification in the reply filed on October 11, 2007 is acknowledged.
2. Based on applicant's elected species, claims 5, 6, 9-21 and 24-29 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-4, 7, 8, 22 and 23 will be examined to the extent they read on the elected species and obvious variants thereof.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite "or a pharmaceutically acceptable salt, solvate or prodrug thereof, in isolation or in a mixture". It is noted that the claims include single stereoisomers and mixtures of said isomers and, thus, it is unclear what is intended by "in isolation or in a mixture".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 7, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lettre et al. (DE 1,084,718).

Lettre et al. teaches secosteroids such as 6-amino-5,6-secocholestane-3 β ,5-diol and 6-dimethylamino-5,6-secocholestane-3 β ,5 β -diol (see cols. 3-4, Examples 1-4; see also attached English abstract, RNs 103099-54-3 and 105520-54-5). The reference teaches the compounds are useful pharmaceuticals (see attached English abstract). The compounds and compositions taught by the reference are encompassed by the instant claims.

7. Claims 1-4, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshida (JP 1,290,624).

Oshida teaches the 5,6-secoosteroids such as 5,6-secocholestane-1,3,6-triol as anticholesteremics and hypolipemics (see the English Abstract, RN 126922-88-1). The compounds and compositions taught by the reference are encompassed by the instant claims.

Claim Objections

8. Claim 8 is objected to as being dependent upon a rejected base claim.


Note: The instant claim would be allowable to the extent it reads on the elected species.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617